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Matthew
Swainson [redacted]
03/12/2010 04:21 PM

To Trevor Byrne [redacted]
cc Mick O'Connor [redacted], Pamela Carter [redacted], Jane Cook [redacted], Larry Kelly [redacted], Virginia Deigan [redacted], Penny Lovell [redacted], Terry Lee [redacted]
bcc

Subject Fw: TRIM: R10/410426 - Fw: RC-2010-RN-01196-3 Proposed product notification letter for cancelled [redacted] thermographic cameras [SEC=IN-CONFIDENCE]

IN-CONFIDENCE

Dear Trevor

I refer to your request for advice to Terry Lee below and attach a copy of the proposed notice with my amendments in track changes. The amendments I recommend are:

- set out a description of the device in full as it appears on the ARTG
- I note that you have decided not to carry out a recall of this device but instead are essentially warning those clinics/users in possession of the device that they cannot advertise its use. Therefore I think that it is important to set out clearly what the clinics cannot do and warn them that penalties may flow if they do not follow the requirements
- lastly I have made a small number of changes to ensure internal consistency in the notice

Discuss with Pam Carter work on for sponsor notification 7/12/10

[redacted] - proposed sponsor notice - reviewed by OLS.DOCX

You have also asked about protocols and templates for publishing in the gazette. We do not have a template for s41KA notices however you may find the attached s30EA useful. Regarding protocols, once you have drafted the notice just provide a copy to OLS with instructions to publish in the gazette. We are happy to provide advice on any draft prior to publication.

section 30EA gazette notice.doc

[redacted]

Happy to discuss further if this would be helpful.

Matt Swainson
Legal Officer
Office of Legal Services
Therapeutic Goods Administration
(02) 6232 8982

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[redacted] has been instructed by the Therapeutic Goods Administration ("TGA") to notify users of thermography equipment supplied by this company (also trading as [redacted]) that **Camera, thermagraphic (MED2000, MED2000 PRO, MED2000 IRIS)** with the **ARTG number 143474** (" the Device") has been removed from the Australian Register of Therapeutic Goods ("ARTG"). Specifically we ask that you note the following:

(i) the ~~Australian Register of Therapeutic Goods~~ entry for the Device ~~(ARTG number 143474)~~ was cancelled from the ~~Register~~ ARTG on 24 September 2010;

(ii) [redacted] requested the Secretary cancel the entry following a request for information and documents from the ~~Therapeutic Goods Administration~~ TGA which included a request for evidence that the Device complied with essential principle 14 set out in the *Therapeutic Goods (Medical Devices) Regulations 2002*. Essential principle 14 ~~(which~~ requires every medical device to have clinical evidence appropriate for the use and classification of the device~~) set out in the *Therapeutic Goods (Medical Devices) Regulations 2002*~~; and

(iii) that ~~you note~~ there are advertising requirements for therapeutic goods and medical devices under the *Therapeutic Goods Act 1989* (the Act), the *Therapeutic Goods Advertising Code 2007* (the Code) and the *Trade Practices Act 1974* (TP Act). These requirements include:

- a person must not publish or broadcast an advertisement about therapeutic goods: if that good is not entered on the ~~Register~~ ARTG (refer to section 42DL(1)(g) of the Act);
- that a therapeutic good cannot be advertised in a manner that is likely to be misleading or likely to lead to consumers inappropriately treating potentially serious diseases (see section 4(2) of the Code); and,
- that goods generally cannot be advertised in a manner that is likely to mislead or deceive (see section 53 of the TP Act).

Please be aware that penalties may apply for breaches of these requirements.

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